

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:

HORNACK, Janmarie, et al.

Serial No. : 09/706,005

Filed: November 3, 2000

DIETARY SUPPLEMENT CONTAINING
ALKALINE ELECTROLYTE BUFFERS

August 6, 2002

Docket No. 30900

Group Art Unit No. 1614

Examiner: R. Davis

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

DECLARATION OF JANMARIE HORNACK

1. I, Janmarie Hornack, am a resident of 9816 Farley Lane, Overland Park, Kansas.
2. I am a named co-inventor of the above identified '005 patent application.
3. I received a Bachelor of Business Administration degree from Florida International University in 1974.

4. Claim 21 of the '005 patent application submitted in applicants' amendment of August 6, 2002, reads as follows:

An improved dietary and/or therapeutic supplement composition consisting essentially of, in combination:

a solid dietary and/or therapeutic supplement agent selected from the group consisting of water soluble vitamins, bioflavonoids, minerals, trace minerals, enzymes, amino acids, whole food products containing phytonutrients, herbs, medicaments, and mixtures of the foregoing that are known to promote health and



well being and each having a pH of 6 or less which upon ingestion with food or a beverage would limit the availability of the agent to the person ingesting the agent; and

an electrolyte additive selected from the group consisting of calcium, magnesium and potassium electrolytes, a sufficient amount of the electrolyte additive being provided in combination with the agent to raise the pH of the combination to a pH of from about 8 to about 12.5 and to maintain the alkaline pH of the supplement composition in the person's stomach upon ingestion of the composition with food or a beverage and during digestion thereof in the person's stomach thereby increasing the effectiveness and utilization of the agent in the person's body.

5. Claims 3, 7, 9 - 16 depend from independent claim 21.
6. Claim 21 and claims 3 and 7, dependent from claim 21 were rejected by the Examiner in an Office Action dated December 17, 2002, as being unpatentable over U.S. Patent No. 6,261,600 to Kirschner, et al.
7. Claims 9 - 13 and 16, dependent from independent claim 21 were objected to only as being dependent from a rejected independent claim (21).
8. Claim 21 recites an improved dietary and/or therapeutic supplement composition, which combines a solid dietary and/or therapeutic supplement agent selected from a defined group of supplements each having a pH of about 6 or less, and a sufficient amount of an electrolyte additive selected of the group consisting of calcium, magnesium and potassium electrolytes to bring the combined therapeutic supplement composition to a pH of from about 8 to about 12.5 to thereby maintain a more alkaline pH of the combined substance at an alkaline pH in the person's

stomach upon ingestion of the composition.

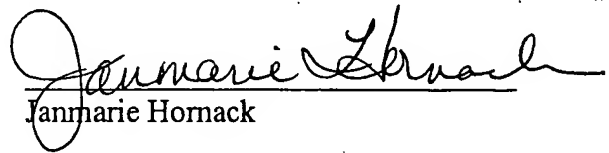
9. I commenced work on improving the effectiveness and utilization of solid dietary and/or therapeutic supplement agents as recited in claim 21 in at least as early as 1995.
10. My earliest efforts commencing in 1995 involved conducting studies of the pH of various dietary and/or therapeutic supplement agents as exemplified by the agents recited in claim 21. As a result of those studies, I became aware that the agents were all of very acidic nature, i.e., generally in the pH range of about 2 to 6.5.
11. My experimental studies with the agents referred to in paragraph 10 and that were conducted in a laboratory at my father's and my residence commencing at least as early as 1995, evolved into efforts to make the agents as set forth in claim 21 more effective and bioavailable.
12. After much effort and trial and error, I ultimately found that by adding a sufficient amount of electrolytes to the low pH dietary and/or therapeutic supplement agents, the effectiveness and bioavailability of the agents upon ingestion was surprisingly improved.
13. I discovered that by adding a sufficient amount of alkaline electrolytes of calcium, magnesium and potassium to dietary and/or therapeutic supplement agents each having a pH of about 6 or less to raise the pH of the combined composition to a pH of from about 8 to about 12.5, two synergistic phenomena are believed to occur. The alkaline pH of the composition results in more rapid digestion of the agent in the cardio fundic portion of the individual's stomach so that within a shorter time than would otherwise be the case, if the composition

were acidic, the majority of the composition is digested. In addition, the presence of the electrolyte factors in the composition also results in an improved intracellular transfer rate of the dietary and/or therapeutic supplement agent.

14. I have regularly kept a record of my experimental studies. Attached hereto as Exhibit A is a copy of the cover sheet of a composition notebook, which contains a written record of certain of my experimental studies. All of the pages of this notebook are permanently bound in place. The first entries in the notebook, Exhibit A, appear in March of 1997.
15. Attached is Exhibit B, a copy of a bound page of the notebook, Exhibit A, which bears my handwritten signature and the date of signing on July 23, 1998, of the page.
16. Exhibit B confirms that at least as early as July 23, 1998, I measured the pH of a number of nutrients of the type identified as being solid dietary and/or therapeutic agents specified in claim 21. In particular, Exhibit B refers to guarana extract, an extract from the seeds of the fruit of a plant that contains guaranine (a phytonutrient), gymnema extract, an extract from an herb containing phytonutrients, soy isoflavone, which is a bioflavonoid, PABA, para-amino benzoic acid, part of a B vitamin complex, garlic, a whole food extract containing phytonutrients and trace minerals, mixed tocopherols, a vitamin and alpha-lipoic acid, an antioxidant. My report of July 23, 1998, indicates that the measured pH of the above combination was about 3.2. I added a sufficient amount of electrolytes, specifically 30 mg of calcium carbonate, 30 mg of magnesium carbonate and 150 mg of potassium carbonate to bring the pH of the total

composition to at least about 8.02.

17. Exhibit B, attached, confirms that I had reduced to practice the entire subject matter of claim 21 prior to April 30, 1999, the 35 U.S.C. § 102(e) effective filing date of the Kirschner, et al., U.S. Patent No. 6,261,600.
18. I further declare that all statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that wilful, false statements and the like are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code.


Janmarie Hornack

Mead
COMPOSITION

100 sheets • 200 pages
9³/₄ x 7¹/₂ in/24.7 x 19.0 cm
wide ruled • 09910

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EXHIBIT

A



Potential Bioav. Nutrients

GUARANA EXT # 150mg

GYM NEMA 5:1 - 60mg

SOY ISOFLAVONE 20mg

PABA 20mg

GARLIC 10mg

MIXED TOCOPHEROLS 10IU

ALA (alpha lipac) 10mg

ABOUT 3.2 pH

ADD Mg CARB, Ca CARB, K CARB. to 7.2 -
then 8.1 - then 8.02

³⁰
~~300~~mg Ca CARB.

30mg Mg CARB.

150mg K CARB.

7/23/98 JH

EXHIBIT

B